

UTAH MEDICAL
PRODUCTS INC.



K 960255

MAR 27 1996

SMDA 510(k) Summary

Trade Name: Ceramic Blade Electrode
Common Name: Electrosurgical Blade
Classification: Electrosurgical Cutting and Coagulation Device and Accessories, 21 CFR 878.4400.

The Utah Medical Products, Inc. (UMP) Ceramic Blade Electrodes (CBE) are intended for use in virtually every surgical discipline where flat, paddle-type electrosurgical blades are used for making straight cuts through tissue. The CBE-2XX blades are intended for use in procedures that require precise cuts where only light or no hemostasis is desired. The CBE-1XX blades are intended for use in procedures where a greater level of hemostasis is desired. When an electrosurgical generator blend mode is used for cutting with the CBE-1XX blades, cauterization of the wound will occur while the cut is being made.

The CBE device is substantially equivalent to the UMP DLP-L11 Loop Electrode (K905263), the Mega Dyne E-Z Clean Blade (K913473), and the Aspen Labs Blade Electrode #60-0180-001 (K780977). The posterior end of the CBE device fits snugly into a standard electrosurgical pen which is connected to an FDA-approved electrosurgical generator. The CBE is used in exactly the same way as the Aspen stainless steel blade and Mega Dyne Teflon®-coated blade electrodes are used for cutting tissues and cauterizing the wound to minimize bleeding. The cutting and cauterization takes place in exactly the same way as with the UMP DLP-L11 Loop Electrode.

Materials that comprise the CBE were selected based on properties of strength, biocompatibility, compatibility with gamma sterilization, conformance with commonly used medical grade plastics and other materials, electrical and thermal properties, ease of processing and low cost. Biocompatibility and sterilization information is available from UMP upon request.

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